Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12594

0 - FRONT

# MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires 12/31/98
See OMB statement on reverse.

FDA use only
Triage unit sequence #: 12594

CESAN Page — of —

## A. Patient information

| 1. Patient identifier | 2. Age at time of event: / or Date of birth: | 3. Sex | 4. Weight |
|---|---|---|---|
| [redacted] In confidence | [redacted] | ☒ female ☐ male | — lbs / 2.7 kgs |

## B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☒ death 10/4/97 (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 10/03/97

4. Date of this report (mo/day/yr): 10/06/97

5. Describe event or problem
THE REPORTER STATED THAT THE PATIENT TOOK AN OTC SUPPLEMENT CALLED "RIP FUEL." THROUGH OUT HER PREGNANCY FOR WEIGHT CONTROL. THE BABY WAS BORN PREMATURE AT 34 WEEK GESTATION WITH A CONDITION KNOWN AS NECROTISING ENTERO COLITIS. THE BABY HAD A DECENTED BELLY WITH NO BOWEL SOUND AND NO URINE OUTPUT. THE INFANT WAS NOT RESPONSIVE TO ANTIBIOTICS AND WAS TRANSFERRED TO ANOTHER HOSPITAL FOR SURGERY. THE INFANTS GUT WAS FOUND TO BE COMPLETELY ISCHEMIC AND DIED SHORTLY AFTER. "RIP FUEL" IS MADE BY TWIN LABS INC. AND KNOWN TO HAVE THE FOLLOWING INGREDIENT: EPHEDRA 330 MG, EPHEDRA ALKALOID 6%, GUARAN, AL-CARONITINE, CHROMOLIN PICOLATE.

6. Relevant tests/laboratory data, including dates
NONE

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
THE BABY WAS BORN PREMATURE. THE MOTHER HAD 6 PREGNANCIES AND HAS 5 LIVING CHILDREN. THE MOTHER SMOKES 1 PACK OF CIGARETTE PER DAY. THE INFANT DIED AFTER 6 DAYS OF LIFE.

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 RIP FUEL - OTC SUPPLEMENT (TWIN LABS INC)
#2

2. Dose, frequency & route used
#1 UKN
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 THROUGH OUT PREGNA
#2

4. Diagnosis for use (indication)
#1 WEIGHT CONTROL
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1 UKN
#2

7. Exp. date (if known)
#1 UKN
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
PRENATAL VITAMINS

RECEIVED OCT 17 1997

## D. Suspect medical device

1. Brand name

2. Type of Device

3. Manufacturer name & address
REC'D. OCT 07 1997

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration Date (mo/day/yr)

6. model # MEDWATCH CTU
catalog #
serial #
lot #
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

## E. Reporter (see confidentiality section on back)

1. Name & Address: [redacted]
Phone #: [redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: RPH

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (1/98) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

**TAKEN BY TELEPHONE**

# Adverse Reaction Information Form A

Complaint Number: CFSAN Project # 12594 Investigator: Joe A. Odom

## Consumer Information

Date of Report: 1/6/98 (MM/DD/YY)

Initial Report Source: ☒ORA Consumer Injury
☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☒F ☐M Age: 6 days

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

## Information on Adverse Reaction

Date of Adverse Reaction:
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): Mother ingested product during pregnancy

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Baby [redacted] born with intestinal abnormalities (see attached memo and medical records)
How long did the symptoms last? six days (baby died after six days of life)
Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.). Mother ingested product during pregnancy. Medical personnel suspected product caused abnormalities)
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: none known

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☐No ☒Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

## Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number:

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? none

What was the medical diagnosis? Necrotizing Entero Colitis
What treatment(s) was given (e.g., drugs, other)? See medical records attached

Were there any preexisting condition(s)/treatment(s)? unknown
(If YES, list them including allergies, and chronic diseases): ☐Yes ☐No

## Product Category

1. Adverse reaction to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids, extracts from animal glands, garlic extract, fish oils, oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin, and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

**Other Product Problems**

2. ☐Foreign Object (specify): _____

3. ☐Other (specify): _____

## Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking):
Ripped Fuel. Mother took product during pregnancy . Have been using the product for four years. Dosage: 2 capsules before morning work out on an empty stomach::: 2 Capsules de--fore afternoon and evening meals. Reason for using: Metabolic enhancer-weight reduction

(see attached memorandum dated 2/17/98)

**List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):**
☐Check here if ingredients are unknown
Ma Huang Extract/(standardized for 334 mg ephedra alkaloids); Gurana Extract 910 mg (standardized for 22% caffeine); L Carnitine 100 mg; Chromium (from Chromium fuel patented chromium picolinate) 200mcg

Mfg. by Twin Laboratories, Ronkonkoma, New York 11779.

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☐Other_____
☒Unknown

☐Color Additive (please specify) _____

Product Label Available: ☐Yes ☒No ☐Unknown Product Sample Available: ☐Yes ☒No ☐Unknown

## Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☒Yes ☐No See attached memorandum dated 2/17/98

Life-Threatening: ☒Yes ☐No

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☒Yes ☐No

Did the adverse reaction result in a congenital anomaly: ☒Yes ☐No

DEPARTMENT OF HEALTH & HUMAN SERVICES

[redacted]

#10662
ATL-DO
#80088

**Date:** January 7,1998

**From:** John D. Lloyd,CSO/ATL-DO

**Subject:** Follow-Up Adverse Event Report
ATL-DO Assgn#80088 of 12/19/97

**To:** Mallory W. Lawrence,SCSO/ATL-DO

I am providing with this memo two of the three items requested by this assignment.These two items are attached as Exhibits#1 and 2. Exhibit#1 is the Adverse Reaction Questionnaire;Exhibit#2 is the associated Medical Record of the Consumer involved.
The original assignment also requested that the labeling associated with the suspect product be collected. Neither the label nor the product was available. On 12/23/97,I informed CFSAN's Monitor for this assignment,Bridgette Wallace,- of the problem with collecting the labeling. Ms. Wallace indicated that the labeling was not necessary.

John D. Lloyd

Exhibits
#1.Adverse Reaction Questionnaire (One Page)
#2.Medical Record of Consumer (Fourteen Pages)

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E N D O R S E M E N T

TO: Chief, Domestic Programs Branch
HFS-636, Division of Enforcement
and Programs
ATTN: Ronald R. Roy

Date: 1-8-98

The medical records and the Adverse Reaction Questionnaire were obtained and are attached to this report.

Mallory W. Lawrence

Mallory W. Lawrence, SCSO
ATL-DO

RECEIVED
MAR 24 1998

O+Attach: CFSAN, HFS-636
Division of Enforcement and Programs
cc: MWL

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date 2/17/98

From Joe A. Odom, Investigator
GRN-RP, ATL-DO

Subject MedWatch 12594 re: Ripped Fuel-Injury

To Mallory W. Lawrence, SCSO
ATL-DO

Atlanta assignment #80051 dated 11/5/97 directed follow up of the above MedWatch report CFSAN #12594 involving Ripped Fuel. The reporter, Ms. [redacted] is a Pharmacist in the Neonatal Intensive Care Unit at [redacted] Phone [redacted]

Ms. [redacted] reported that a patient took the OTC supplement Ripped Fuel during her pregnancy. The baby was born premature at 34 weeks with Necrotizing Enterocolitis. The baby had a decented belly with no bowel sounds and no urine output. The baby was not responsive to antibiotics and was transferred to another hospital, [redacted] for surgery. Surgery found the infant's gut was completely ischemic and the baby died shortly after. The infant survived for six days.

On 1/6/98 I called Ms. [redacted] office. I requested that she contact the patient and inform her of FDA's intention to perform an investigation. I also requested identification of the patient. Ms. [redacted] said that she is an RPh assigned to the Neonatal Intensive Care Unit of the hospital. She also stated that as the NICU Pharmacist she accompanies the physicians and interns on their "rounds" within the unit.

On 1/7/98 Ms. [redacted] called the Resident Post and gave me the patient's name [redacted] and the patient's phone number [redacted]. I then made several attempts to call Ms. [redacted].

On 1/8/98 I made several more calls before contacting Ms. [redacted] and setting an appointment for the following day.

On 1/9/98 I visited Ms. [redacted] Credentials were shown to Mrs. [redacted] and I explained the nature of my visit. Ms. [redacted] stated the she still use the "Ripped Fuel" product. I asked how long has she been using the product and she said that she has been

using ripped fuel for four (4) years. She had in her possession an opened bottle of the product which originally had 200 capsules. The bottle had a warning statement which read in part: do not use if you are pregnant or nursing. I asked Ms [redacted] if she read the warning. She said that aspirin has warnings on it too. I then asked Ms. [redacted] if she took the product during her pregnancy and she said yes. She stated that she has been using the product for four (4) years. She also said that she used the product during her pregnancy with [redacted] (her small son who was running and playing in the room). She said that [redacted] was two years old this past November (1997) and he did not have anything wrong with him. I asked and Ms. [redacted] signed three (3) Authorization for Medical Records Disclosures. One for her medical records and two for her daughter, [redacted] medical records. Ms. [redacted] did not have an empty bottle for label collection. However, a check of local health food stores, by phone, found this product for sale. The product is manufactured by Twin Laboratories,Ronkonkoma, N.Y. 11779.

On 1/20/98 I visited the [redacted]. Credentials were shown to the medical records technician Ms. [redacted] and I explained the reasons for the visit. The Authorization for Medical Records Disclosures were presented listing the requests for Mrs. [redacted] and her deceased daughter [redacted] medical records. The medical records for [redacted] was obtained and is enclosed as attachment #1. The medical records for her daughter, [redacted] could not be found. Ms. [redacted] stated that the records could not be found and that a search will have to be made.

I then visited the [redacted] medical records section. Credentials were shown to the medical records technician and I explained the reason for my visit. I obtained Ms. [redacted] daughter, [redacted] medical records from the [redacted] and they are enclosed as attachment #2.

I contacted the [redacted] medical records section several different times. On 2/11/98 Ms. [redacted] Medical records Tech. called the [redacted] Resident Post. She informed me that the medical records for [redacted] had been found and copies were ready for collection. On 2/13/98 Investigator Teresa Thompson from the [redacted] Resident Post was at the hospital medical records department collecting records on another injury investigation. She obtained [redacted] medical records and brought them to the resident post. These medical records are enclosed as attachment #3.

According to the [redacted] medical records, the infant was evaluated and an emergent operation was performed. The laparotomy found that the infant had a completely necrotic colon down to the sigmoid and her small bowel was entirely necrotic except for six inches of jejunum. The surgeon felt this was incompatible with life. The abdomen was closed after the purulent pus and stool which was free within the abdomen was sucked out.

The infant was left intubated and was made comfortable with a fentanyl drip. After the Surgeon had consultation with the family, the ventilator was removed and the infant died within one hour.

ENCLOSURES

1. Medical Records from [redacted] for [redacted]
2. Medical Records from [redacted] for [redacted]
3. Medical Records from [redacted] for [redacted]
4. Adverse Reaction information Form A.
5. Copy of assign #80051 dated 11/5/97

Joe D. Odom

Joe Odom, Investigator
[redacted]
Atlanta District